ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 04/25/12 for the Period Ending 04/25/12

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
CIK	0001008848
Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **April 25, 2012**

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50513**	**13-3831168**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

15 Skyline Drive, Hawthorne, NY	**10532**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(914) 347-4300**

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On April 25, 2012, Acorda Therapeutics, Inc. issued a press release announcing that it presented data showing that the increase in walking speed demonstrated by people with multiple sclerosis (MS) who responded to treatment with AMPYRA ® during three-month Phase 3 clinical trials was also observed for up to five years in open-label extension studies. In addition, the long-term safety and tolerability of AMPYRA was consistent with that observed in clinical trials, with no new safety signals emerging. These data, from open-label extension studies of AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, were presented at the 64 th American Academy of Neurology Meeting in New Orleans, LA. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	*Description*
99.1	Press Release dated April 25, 2012

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Acorda Therapeutics, Inc.

April 25, 2012

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated April 25, 2012

CONTACT:

Jeff Macdonald
Acorda Therapeutics
(914) 347-4300 ext. 4232
jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda Therapeutics Presents AMPYRA ® Long-Term Safety and Efficacy Data at 64 th American Academy of Neurology Annual Meeting

HAWTHORNE, N.Y. – April 25, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today presented data showing that the increase in walking speed demonstrated by people with multiple sclerosis (MS) who responded to treatment with AMPYRA ® during three-month Phase 3 clinical trials was also observed for up to five years in open-label extension studies. In addition, the long-term safety and tolerability of AMPYRA was consistent with that observed in clinical trials, with no new safety signals emerging. These data, from open-label extension studies of AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, were presented at the 64 th American Academy of Neurology Meeting in New Orleans, LA.

“The progressive nature of MS, despite treatment with medications, continually degrades the walking ability of the majority of people with this disease. Walking impairment is a major issue for people with MS and their families and caregivers, as they all contend with an individual’s progressive walking impairment over time,” said Ron Cohen, M.D, president and CEO of Acorda Therapeutics, Inc. “These long-term data support the use of AMPYRA as a chronic therapy, showing that people with MS may experience improvements in their walking ability for a considerable period of time.”

The poster, entitled “Final Data from Open-Label Extension Studies of Dalfampridine Extended Release Tablets in Multiple Sclerosis” (Poster P04.128), reported data from a total of 483 participants who competed either of two Phase 3 AMPYRA clinical trials and elected to enroll in an open-label extension study of that trial. The extension studies were open to all participants who completed the Phase 3 clinical trials, regardless of treatment with AMPYRA or placebo, or whether they were AMPYRA responders or non-responders.

Initial assessments were made during a baseline screening visit at the start of the extension studies. Visit 1 was held two weeks after screening, with subsequent assessments at 2, 14 and 26 weeks, and then every 6 months. Efficacy was assessed using the Timed 25-Foot Walk (T25FW), and safety was monitored by routine adverse event reporting, laboratory test results, and ECG monitoring.

During the open-label extension, patients who were responsive to AMPYRA in the Phase 3 parent studies continued to show improvements in walking speed relative to non-responders for up to 5 years, which was the maximum drug exposure in the open-label studies. There was an overall decline in walking speed observed over the course of the extension studies in all patient groups, which is consistent with the natural MS disease progression that has been previously reported.

Across the two extension studies, the most common adverse events were urinary tract infections, falls, MS relapses, arthralgia, and peripheral edema. There were four seizure-related adverse events reported in the extension studies among the patients who were treated with AMPYRA in the parent trial and subsequently enrolled in the extension (1.3%). Three of these events were convulsions, and one was a partial complex seizure. These rates are similar to reported seizure rates in the general MS population.

AMPYRA is the only FDA-approved therapy to improve walking in people with MS. This was demonstrated by an improvement in walking speed as measured by the T25FW.

AMPYRA is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA ®) in some countries outside the United States.

Important Safety Information
AMPYRA can cause seizures; the risk of seizures increases with increasing AMPYRA doses. AMPYRA is contraindicated in patients with a prior history of seizure. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl ≤ 50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51-80 mL/min) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated CrCl should be known before initiating treatment with AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

The most common adverse events (incidence greater-than or equal to 2% and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

For full U.S. Prescribing Information and Medication Guide for AMPYRA, please visit: www.AMPYRA.com

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES® (tizanidine hydrochloride) and ZANAFLEX® (tizanidine hydrochloride) tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride tablets, an authorized generic version of ZANAFLEX CAPSULES distributed by Watson Pharmaceutics, Inc. under its agreement with Acorda.

Acorda is developing an industry-leading pipeline of novel neurological therapies. The Company is studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional preclinical programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and uncertainties that could cause actual results to differ materially, including our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including any acquired or in-licensed programs; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and the ability to obtain additional financing to support our operations. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda Therapeutics may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this release are made only as of the date hereof, and Acorda Therapeutics disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

###